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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/901,938 | 07/10/2001 | Michael Econis | 053884-5001 | 9281 |
| 28977 | 7590 | 05/31/2005 | EXAMINER | |
| MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921 | | | SAOUD, CHRISTINE J | |
| | | ART UNIT | PAPER NUMBER | |
| | | | 1647 | |

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/901,938 | ECONS ET AL. |
| | Examiner | Art Unit |
| | Christine J. Saoud | 1647 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 January 2005.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-35 and 39-83 is/are pending in the application.
 4a) Of the above claim(s) 17-31,34,35,39-42 and 44-83 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12,14-16,32,33 and 43 is/are rejected.
 7) Claim(s) 13 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1 and 12 have been amended and claims 36-38 have been cancelled as requested in the amendment of 19 January 2005. Claims 1-35 and 39-83 are pending in the instant application. Claims 17-31, 34-35, 39-42, 44-83 remain withdrawn as being drawn to a nonelected invention, said election made without traverse in Paper No. 8. Claims 1-16, 32-33, and 43 are under examination in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 19 January 2005 have been fully considered but they are not deemed to be persuasive.

Petition Filed Under 37 C.F.R. § 1.59(b)

Applicant's petition filed 19 January 2005 is noted. This petition has been forwarded to SPRE Dixon for consideration.

The Examiner maintains that the content of the Interview summary mailed 23 July 2004 is accurate. The entry of an Examiner's amendment to place an application

in condition for allowance does not require a withdrawal of finality. When an Examiner's amendment is entered into an application in order to place it into condition for allowance, finality is not withdrawn. Entry of an Examiner's amendment to place an application in condition for allowance closes prosecution, so withdrawal of finality would be a moot point. Applicant insisted on the finality being withdrawn and a new Office action being issued. If the Examiner's amendment had been authorized, it would have been made and entered into the instant application.

Claim Rejections - 35 USC § 112

Claims 1-11, 32 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 43 recite "has/having the biological activity of FGF23". However, upon reading the instant specification, the term "FGF23" is intended to encompass molecules of different structure (variants, mutants, homologs, % identity similarity, etc.), and therefore, different activities. Therefore, there is insufficient antecedent basis for "the biological activity of FGF23" since a fair reading of the specification would indicate that "FGF23" has more than one activity. Applicant may wish to amend the claims to include a biological activity so that the metes and bounds of the claims can be determined. Claims 5-11 and 32 are indefinite for depending from indefinite claims.

Applicant argues the rejection at page 16 of the response and points to page 24 of the specification describing wild type and mutant FGF23 molecules. However, this

further supports the rejection. The claim reads “the biological activity of FGF23” and “FGF23” is intended to encompass different molecules with different activities. Since the skilled artisan does not know which FGF23 molecule is intended by the claims, they clearly do not know which activity is intended by the claims and therefore, the metes and bounds of the claims cannot be determined. Applicant asserts that the basic property of FGF23 is the “ability of a molecule to bind an FGF receptor and alter phosphate transport”. However, if an FGF23 mutant is generated which has 98% identity with SEQ ID NO:2, but does not bind the receptor, is it encompassed by the claims? If an FGF23 mutant is generated which has 98% identity with SEQ ID NO:2, binds the receptor but antagonizes phosphate transport, is it encompassed by the claims? If an FGF23 mutant is generated which has 98% identity with SEQ ID NO:2, binds the receptor but agonizes phosphate transport, is it encompassed by the claims? The skilled artisan cannot make this determination because the claims fail to indicate what biological activity is intended and the breadth of “FGF23” is such that molecules with different biological activities are encompassed.

This ground of rejection could be avoided by including (1) the activity that is intended or (2) indicating which FGF23 molecule the biological activity is to be compared to (i.e. FGF23 having the amino acid sequence of SEQ ID NO:2).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-4, 12, 14-16 and 33 rejected under 35 U.S.C. 102(e) as being anticipated by either US 2002/0082205 A1 (Itoh et al.) or US 2002/0102604 A1 (Milne Edwards et al.).

Itoh et al. teach and claim a protein which is encoded by a nucleic acid wherein the encoded protein is 100% identical to the protein of the instant application. The effective filing date of Itoh et al. is 08 March 2000, which is prior to Applicant's effective filing date of 19 July 2000, making the reference prior art under 102(e). See Itoh et al.'s SEQ ID NO:4 (protein) and SEQ ID NO:3(nucleic acid). Itoh et al. also disclose compositions comprising the nucleic acid beginning at paragraph [0093]. Itoh et al. further disclose vectors, vectors linked to promoter and/or regulatory sequences and recombinant cells comprising the vector (see claims 7-10).

Milne Edwards et al. teach and claim a nucleic acid molecule (SEQ ID NO :57) which encodes a protein (SEQ ID NO :298) which is 100% identical to the protein of the instant application. The nucleic acid molecule of Milne Edwards et al. is shorter than the nucleic acid molecule of SEQ ID NO:1 of the instant application, but is 99.9% identical over a stretch of 1240 bases, which includes the protein coding region. The effective filing date of Milne Edwards et al. is 08 December 1999, which is prior to Applicant's effective filing date of 19 July 2000, making the reference prior art under

102(e). Milne Edwards et al. additionally disclose compositions comprising the nucleic acid and an acceptable carrier (see at least paragraph [0540]). Milne Edwards et al. further disclose vectors, vectors linked to promoter and/or regulatory sequences and recombinant cells comprising the vector (see claims 8-10). Therefore, the instant claims are anticipated by the prior art.

Applicant argues the instant rejections by stating "the Examiner's rejections under 35 U.S.C. § 102(e) are properly directed to only one polypeptide of the presently-claimed invention, namely, the polypeptide set forth in SEQ ID NO:2". However, to reject the claims on the basis of anticipation, the prior art need only disclose one embodiment of the claimed invention. Where some of the claims are directed to molecules having 98% identity (genus claim), a species (i.e. a protein with a given amino acid sequence identical to SEQ ID NO:2) anticipates the claims.

The Declaration filed on 19 January 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Itoh et al. and Milne Edwards et al. references.

MPEP 715.05 states "[w]hen the reference in question is a noncommonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 CFR 1.608 instead of 37 CFR 1.131." The rules regarding 37 CFR 1.608 have been changed as of Aug. 12, 2004 (Federal Register, Vol. 69, No. 155) and are not reflected in the current version of the MPEP. Applicant is referred to § 41.202

Allowable Subject Matter

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

The inclusion of claims 14-16 in the rejection over prior art was inadvertently missed in the previous Office action. Therefore, based on the new ground of rejection, the instant Office action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAoud
PRIMARY EXAMINER

